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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/715,902	11/17/2000	John James Donnelly	1627.003	5612

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Chiron Corporation
Intellectual Property - R440
P.O. Box 8097
Emeryville, CA 94662-8097

EXAMINER

WEHBE, ANNE MARIE SABRINA

ART UNIT PAPER NUMBER

1633

DATE MAILED: 11/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/715,902

Applicant(s)

DONNELLY ET AL.

Examiner

Anne Marie S. Wehbe

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 September 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16, 18-23, 29-31, 33-44, 46, 50 and 52-54 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16, 18-23, 29-31, 33-44, 46, 50, and 52-54 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

A request for continued examination (RCE) under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/26/05 has been entered. As requested, applicant's amendment and arguments received on 9/26/05 have also been entered. Claims 17, 24-28, 32, 45, 47-49, and 51 are canceled. New claims 54 has been added. Claims 1-16, 18-23, 29-31, 33-44, 46, 50, and 52-54 are currently pending and under examination. An action on the merits follows.

Those sections of Title 35, US code, not included in this action, can be found in previous office actions.

Claim Rejections - 35 USC 103

The rejection of pending and new claims 1-16, 18-23, 29-31, 33-44, 46, 50, and 52-54 under 35 U.S.C. 103(a) as being unpatentable over WO 97/24447, 7/10/97, hereafter referred to as Song et al., in view of US Patent No. 5,783,567 (7/21/98), hereafter referred to as Hedley et al., and further in view of Fattal et al. (1998) J. Controlled Rel., Vol. 53, 137-143, is maintained. Applicant's arguments have been fully considered but have not been found persuasive in

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overcoming the instant grounds of rejection of the claims for reasons of record as discussed in detail below.

The applicant has not made any claim amendments to the previously pending claims. New claim 54 recites the same method as claim 1 with the exception that claim 54 does not place any limitation on how the transfection agent is formed. Thus, new claim 54 is broader than previously pending claim 1.

The applicant's arguments in the response filed on 9/26/05 with the RCE refer the examiner to the arguments presented in the after-final response received on 12/14/04, which was the subject of the advisory action mailed to applicants on 1/21/05. The applicant states that the remarks presented in the 12/14/04 response overcome the rejection of the previously pending claims and new claim 54. In response, applicant's remarks made in the 12/14/04 response were considered by the examiner and not found persuasive as discussed in detail in the advisory action. The discussion presented in the advisory action is reiterated below.

The applicant argues that the particles taught by Fattal et al. are nanoparticles, not microparticles as claimed, or as taught in Hedley. In response, please note that the claims as written encompass the same size particles as taught by Fattal et al., see for example instant claim 30 which depends on independent claim 1 and recites that the microparticles have diameters ranging from "about 500 nm to about 30 um". Thus, the "microparticles" of the instant claims clearly encompass particles of "about 500 nm". Note as well that the term "about" is relative and as such "about" 500 nm reads on particles which are less than 500 nm. Fattal et al. teaches particles which are "about" 500nm in diameter. Further, please note that the compositions of microparticles taught by Hedley et al. include particles of about 500nm as well, see for example

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Figure 2 of Hedley et al. Thus, both references, Hedley et al. and Fattal et al. teach particles that meet the claim limitations in terms of size.

The applicant further argues that because of the alleged size difference in the particles taught by Hedley et al. and those of Fattal et al., the Fattal et al. particles would not be phagocytosed, and thus there would be no motivation to combine the teachings of Fattal et al. with Hedley et al. In response, the art, including the Mukherjee et al. reference provided by applicants, teaches that cells use several different methods to uptake foreign matter, including phagocytosis and endocytosis. The claims as written do not include any limitation as to the mechanism by which the microparticles enter the dendritic cells. At the time of filing, particles of many different sizes were known to be successfully taken up by cells. In fact, both Hedley et al. and Fattal et al. demonstrate successful uptake of particles of different sizes comprising nucleic acids by cells. Thus, the art of record shows that both particles less than 1 μm and particles greater than 1 μm can successfully deliver nucleic acids into cells. Furthermore, please note that Fattal et al. does in fact teach that the nanoparticles are taken up by cells via an endocytic/phagocytic pathway (Fattal et al., page 137, abstract). In addition, and as stated in the previous office actions, Fattal et al. provides motivation to include cationic detergent in particles for nucleic acid delivery by teaching that the inclusion of cationic detergent increases the amount of polynucleotide associated with the particles and increases the cellular uptake of these particles by cells.

Finally, the applicant argues that since Fattal et al. teaches the delivery of oligonucleotides, not expression vectors, there is no reasonable expectation of success that vectors introduced using the methods of Fattal et al. would in fact be expressed. In response, the

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previous office action discussed the fact that the prior art demonstrates that many different methods are useful for introducing expression vectors into cells. The art further demonstrates that once in the cell, the vector expresses any encoded gene which is operably linked to appropriate expression elements, see Yang et al., Manickan et al., Spahn et al., and Tuting et al. cited as rebuttal evidence to arguments/evidence presented by the applicants in the office action mailed on 12/18/03. In addition, both Song et al. and Hedley et al. provide specific examples of gene expression after the uptake of expression vectors via different routes such as introduction by viruses, liposomes, and microparticles. As a result, the skilled artisan would reasonably expect that successful delivery of an expression vector into a cell would be followed by gene expression. Since Fattal et al. demonstrates the successful delivery of nucleic acid into cells using particles containing cationic detergents, the skilled artisan would therefore have had a reasonable expectation of success that delivery of expressible nucleic acids using the same technique would in fact result in gene expression. As such, applicant's arguments are not found persuasive and the rejection of record stands.

No claims are allowed.

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114.

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See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication from the examiner should be directed to Anne Marie S. Wehbé, Ph.D., whose telephone number is (571) 272-0737. The examiner can be reached Monday- Friday from 10:30-7:00 EST. If the examiner is not available, the examiner's supervisor, Dave Nguyen, can be reached at (571) 272-0731. For all official communications, **the new technology center fax number is (571) 273-8300**. Please note that all official communications and responses sent by fax must be directed to the technology center fax number. For informal, non-official communications only, the examiner's direct fax number is (571) 273-0737. For any inquiry of a general nature, please call (571) 272-0547.

The applicant can also consult the USPTO's Patent Application Information Retrieval system (PAIR) on the internet for patent application status and history information, and for electronic images of applications. For questions or problems related to PAIR, please call the USPTO Patent Electronic Business Center (Patent EBC) toll free at 1-866-217-9197.

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Representatives are available daily from 6am to midnight (EST). When calling please have your application serial number or patent number available. For all other customer support, please call the USPTO call center (UCC) at 1-800-786-9199.

Dr. A.M.S. Wehbé

A handwritten signature in black ink, appearing to read 'Anne M. Wehbe', with a long horizontal stroke extending to the right.

ANNE M. WEHBE' PH.D
PRIMARY EXAMINER